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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,059	02/16/2001	Ronald C. Montelaro	A33577 072396.0217	4780

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EXAMINER

LIU, SAMUEL W

ART UNIT PAPER NUMBER

1653

DATE MAILED: 03/11/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,059

Applicant(s)

MONTELARO ET AL.

Examiner

Samuel W Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The response filed 13 December 2002 (Paper No. 8) as to amendment of claims 2, 10, 13 and 27, and Applicant's request for extension of time of one months filed 13 December 2002 (Paper No. 7) has been entered. The following is applicable to the pending claims 1-27. The revised drawing (filed 16 February 2001) according to the "Notice of Draftperson's Patent review has been received.

Note that the grounds of objection and/or rejection not explicitly stated and/or set forth below are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the term "having" which is an open-ended as opposed to the closed term "consisting of". The claim is unclear as to whether or not the claimed peptides encompassed any polypeptide segment(s) or any peptidomic molecule comprising amino acid sequences SEQ ID NO:1-3, and whether or not the claimed compositions include conjugates wherein the peptide is linked to a cargo molecule, *e.g.*, protein, enzyme or non-peptide compound such as antibiotic, as set forth in the specification (see [0065]). Applicant is also referred to the following section of

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"Response to the rejection under 35 USC 112, the second paragraph" for the more details in this regard. See also claims 3, 5 and 7. The dependent claims are also rejected.

Claim 18 recites "at least one cysteine residue"; the recitation is unclear as to whether or not unrecited cysteines or cysteine-containing fragments additionally attached to the peptides because all the peptides (SEQ ID NOs: 1-3) does not contain plurality of cysteine residues.

Response to the rejection under 35 USC 112, the second paragraph

The response filed 13 December 2002 asserts that the term "having" on claim 1 is not indefinite because the specification teaches that the peptides of the present application may be linked to a cargo, e.g., lysozyme (see page 5, the second paragraph). The applicant's argument is unpersuasive because the claims of the current application are directed to the disclosed antimicrobial peptides *per se* not to proteinaceous cargo molecule, e.g., the lysozyme protein.

It should be stressed that the present claims as disclosed is not directed to any unrecited subject matter, i.e., N- or C-terminus of the claimed peptides are linked to any macromolecule, e.g., lysozyme, and non-proteinaceous antibiotic compounds, e.g., antibiotic such as penicillin that acts as a cargo, as argued in the applicant's response (see the response at page 5, and the specification, [0065]). In light of this regard, the recitation "having" renders the claims indefinite.

Also, the response asserts the recitation of "at least one cysteine" of claim 18 is not indefinite; such the assertion relies on the open language "having" in claim 1 from which

4/ Invented suggests to them to use "comprising or consisting of"

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claim 8 depends. The applicant's argument is not persuasive because of the "having" renders claim 1 indefinite (see the statement *supra*).

Provisional Rejection - Obviousness Type Double Patenting

Claims 1-27 of this application conflict with claims 2-7, 25-28, 35, 38-40, 54-55 and 62 of Application No. 10079075. Note that this rejection is made in view of the pending claims of the current disclosure of 10079075 based on preliminary amendment filed 13 December 2002 (Paper No. 3). 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 1-27 (renumbered, see the foregoing statement) of the instant application are provisionally rejected under the judicially created doctrine of double patenting over claims 2-7, 25-28, 35, 38-40, 54-55 and 62 of Application No. 10079075. This is a

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provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced application and would be covered by any patent granted on that application since the referenced application and the instant application are claiming common subject matter, as follows:

Claims 2, 4 and 6 of Application 10079075 disclose the common subject matter of claim 1 of the current application despite with different scope.

Claims 3, 5 and 7 of Application 10079075 disclose the common subject matter of claim 2 of the current application despite different scope.

Claims 2-7 of Application 10079075 disclose the same subject matter of claims 3-8 of the current application, respectively.

Claims 25, 27, 28 of Application 10079075 disclose the common subject matter of claims 9, 10 and 11 of the current application.

The disclosure of Application 1007950 expressly sets forth that “the peptides of the present invention are useful as coatings on implanted devices, such as prostheses, *e.g.*, prosthetic joints” (see [0091]), and provides an example as to the antimicrobial peptide, *i.e.*, SEQ ID NO:2 that is bound to a solid phase substrate, *e.g.*, an Affigel.TM. 15 resin, or a prosthetic joint (see [0091]); thus, claim 35 of Application 10079075 is an obvious variation over claims 12-17 and 26 of the current application.

Claims 38 and 39 of Application 10079075 disclose the common subject matter of claims 18-19 of the current application.

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Since the disclosure of Application 1007950 sets forth that the peptides of the present invention is directed to a peptide-cargo complex wherein the peptides is attached to a cargo to allow for the delivery of the cargo into a target microorganism so as to increase the antimicrobial activity of the claimed peptides, claim 40 of Application 10079075 is an obvious variation over claims 20-21 of the current application.

The disclosure of Application 1007950 discloses a method for inhibiting microbial growth comprising administering a subject the claimed antimicrobial peptides (see claim 42, and Example 2), especially exemplifies the antimicrobial activity of LSA-5 peptide, i.e., SEQ ID NO:2 (see Table 3), Thus, claim 40 of Application 10079075 is an obvious variation over claims 22 and 24 of the current application.

The disclosure of Application 1007950 sets forth a method for inhibiting microbial growth in cell culture comprising contacting the cells with the claimed antimicrobial peptides (see claim 54) and further exemplifies use of the peptide, i.e., WLSA-5, i.e., SEQ ID NO:3 (see [0088], and Figure 9 where demonstrates that increasing concentrations of SEQ ID NO:3 peptide decrease in bacterial viability in the culture cells). Thus, claim 54 of Application 10079075 is an obvious variation over claims 23-24 of the current application.

The disclosure of Application 1007950 sets forth that in the claimed method, the microbe is resistant to antibiotics (see claim 62); and further, the specification explicitly sets forth the example that the SEQ ID NO:3 peptide is highly active against antibiotic (penicillin)-resistant strain, e.g., *S. aureus* (see [0089] and example 4). Thus, claim 62 of Application 1007950 is an obvious variation of claim 27 of the current application.

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The disclosure of Application 1007950 sets forth that in the claimed method, the peptide is administered enterally or parenterally (see claim 55), and the specification further sets forth the claimed antimicrobial peptides are administered the same (see [0070]) and explicitly sets forth an example that the SEQ ID NO:3 peptide is administered intraarticularly, which meets the limitation of 1007950 disclosure stated above. Therefore, claim 55 of Application 1007950 is an obvious variation of claim 25 of the current application.

Note that claims 22-27 have been renumbered (see the previous Office action).

It is therefore concluded that the claims of the present application are not patentably distinct from the claims of Application 10079075 as they are the obvious variations each other.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Response to the rejection Provisional Rejection - Obviousness Type Double Patenting

The response filed 13 December 2002 asserts that applicant has most recently amended claims of Application 10079075 so that the amendment would render the Provisional Rejection - Obviousness Type Double Patenting moot. The applicant's argument is fully considered but it is found unpersuasive. Although the peptide sequences

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of SEQ ID NOs: 1-3 have been deleted from claims 1, 35, 40, 42, 51, 54 and 63 of Application 10079075 by the applicant's amendment filed 13 December 2002, the rejection stands since the subject matter set forth in the disclosure especially in claims 2-7 of Application 10079075 represents an obvious variation over the claims of the instant application (see the statement *supra*). Thus, the rejection under obviousness type double patenting is maintained.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If

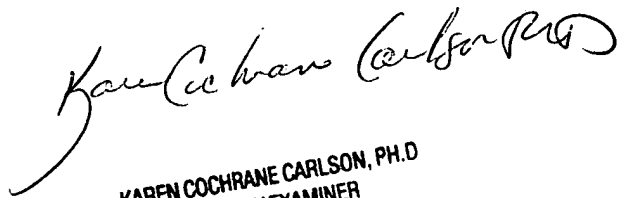
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attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, PhD.

February 26, 2002



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER